

Application No. 10/050,664
Amendment "B" dated June 13, 2005
Reply to Office Action mailed May 24, 2005

REMARKS

Claims 1-25, 27 and 28 are pending in the application, wherein claims 1, 12, 20, 25 and 27 have been amended, claim 26 was cancelled, and new claim 28 was added. The claims have been amended in response to the various rejections. Applicants respectfully request favorable consideration and allowance of the application in view of the foregoing amendment and the following remarks.

Claim 1 has been amended to incorporate from original claim 12 the act of "introducing a viscous disinfecting composition into the root canal in a controlled manner using an endodontic file". The use of an endodontic file to introduce the disinfecting composition in a controlled manner is an advancement over the art, particularly the art cited in the office action. With regard to Hahn (US 6,139,320), the method of claim 1 provides for much more controlled application of the disinfecting composition compared to the oscillating device disclosed in Hahn. As shown on the front cover of Hahn, a nozzle 46 located external to the tooth being treated is used to provide an externally generated spray of a liquid composition 48 onto the surface of an oscillating abrasive tool 36. Hahn, in fact, discloses a wide variety of different embodiments, each of which is designed for its own unique purpose. Each is designed to work on a different portion of a tooth. Only one embodiment is described as being suitable for treating a root canal. Figure 14 depicts the only tool described by Hahn as being suitable for treating a root canal (or "root channel"). Col. 11, lines 17-19; col. 16, line 60 -- col. 17, line 22. As in the embodiment of Figure 3, the root canal device of Figure 14 includes an nozzle 46 located external to the tooth, and therefore the root canal, which is used to spray a liquid 48 onto an outer surface of a powered oscillating root canal tool 156. The portion of the tool 156 onto which the liquid 48 is sprayed using nozzle 46 is also located outside the tooth. It is readily apparent from Figure 14 that the liquid spray cannot be confined to just the root canal of the tooth. There is a high likelihood of overspray of liquid 48 onto surrounding tissues (*i.e.*, not all of the liquid spray 48 emitting from nozzle 46 will likely only contact and remain on tool 156).

The method of claim 1 provides for much more controlled application of a disinfecting composition compared to the externally located spray nozzle shown in Figure 14 of Hahn. Moreover, a critical feature of Hahn is the use of one of the several oscillating devices disclosed therein for treating a tooth, which are intended to take the place of conventional dental hand pieces used with rotating drills or burs. When treating a root canal, it is critical to the invention

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of Hahn to use the specially designed oscillating tool shown in Figure 14. It would be contrary to Hahn to entirely eliminate the oscillating device of Figure 14 in favor of an ordinary endodontic file. Accordingly, Hahn teaches away from introducing a disinfecting composition into a root canal using an endodontic file as recited in claim 1 as now amended.

None of the other references cited in the Office Action teach or suggest introducing a disinfecting composition into a root canal using an endodontic file. Citing Nance (US 6,638,064), the Office Action observes that:

endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite.

Office Action, page 7 (emphasis added). Thus, while it may be known to clean a root canal using an endodontic file, followed by irrigating the root canal using a dilute solution of sodium hypochlorite to further disinfect it, it was not heretofore known to introduce a viscous disinfecting composition into a root canal using an endodontic file.

Moreover, Nance neither teaches nor suggests introducing a disinfecting composition into a tooth using an endodontic file. The "endodontic instrument" disclosed in Nance is not a "file" but a hollow "needle" used solely for injecting an irrigant into a root canal following treatment with an endodontic file: "The claimed invention is particularly useful in irrigating a root canal". Col. 3, lines 46-47 (emphasis added). "The insertion of the shank is followed by transferring a fluid, by way of the needle, from the crown of the tooth along the non-linear central axis of the root canal to a discharge point adjacent the apical foramina. Thereafter, the fluid is discharged from an orifice at the distal end of the needle". Col. 6, lines 18-23 (emphasis added). Accordingly, even if Nance were combined with Hahn, the combined teachings neither teach nor suggest a method in which a viscous disinfecting composition is introduced into a root canal using an endodontic file. Accordingly, Applicants respectfully request reconsideration of the rejection to claim 1 as well as the claims which depend therefrom.

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Claim 20 was alternatively amended to recite a method of disinfecting a root canal using a viscous disinfecting composition that comprises the mixture products of sodium hypochlorite, water, a gelling agent, and a base. The term "mixture products" was used to account for the fact that the base may react with the sodium hypochlorite, gelling agent, and/or water. None of the cited references teach or suggest a disinfecting composition that is formed using these ingredients.

Claim 20 was further amended to specify that the gelling agent is "included in an amount in order for the disinfecting composition to have a viscosity sufficient to remain in place within the root canal and disinfect accessory canals prior to rinsing". A method in which the inventive composition remains in place within the root canal and disinfects accessory canals prior to rinsing is taught in the Application at page 26, lines 9-11. Claim 20 was also amended to specify that the "base" is included "in an amount so as to raise the pH of the disinfecting composition in order to increase stability of the sodium hypochlorite while not substantially destroying gel stability of the gelling agent". Support for this is found at page 11, lines 11-22 of the Application.

As discussed in the Application at page 11, lines 11-22, there is a delicate balance between the pH and its affect on the stability of sodium hypochlorite, on the one hand, and the gel stability of the gelling agent, on the other. This delicate balance is another inventive aspect discovered by the inventors. None of the cited references understands this delicate balance. Because claim 20 recites the use of a composition that includes an amount of base that accounts for the delicate balance between stability of sodium hypochlorite, on the one hand, and the gel stability of the gelling agent, on the other, Applicants submit that claim 20 is unobvious over the art of record.

The Office Action does not point to any teaching or suggestion in the art regarding the tradeoff and balance between stability of sodium hypochlorite, on the one hand, and the gel stability of the gelling agent, on the other. Instead, it characterizes such features as "well-known" and therefore obvious without providing any evidence in support of this assertion. Even assuming for the sake of argument that it were well-known that sodium hypochlorite stability increases with increasing pH, and that gel stability increases with decreasing pH, the Office Action has pointed to no teaching or suggestion in the art that would identify or motivate the use of any particular pH range to achieve a balance between sodium hypochlorite stability, on the

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one hand, and gel stability, on the other. To find this balance would require undo testing and is therefore not obvious as a matter of law. More fundamentally, a *prima facie* obviousness rejection requires some suggestion or motivation *in the prior art*, not applicant's own disclosure, to achieve this critical balance. No such showing has been made. Accordingly, claim 20 as amended is believed to be unobvious over the art of record.

Finally, claim 25 was amended to claim the use of a composition that comprises the mixture products of sodium hypochlorite, water, a gelling agent, and a base, but within the more preferred ranges for sodium hypochlorite, gelling agent, and pH that have been found optimal for disinfecting a root canal. The combination of such ranges within a viscous disinfecting composition are neither taught nor suggested in the cited art. Accordingly, claim 25 is not *prima facie* obvious over the art of record. Moreover, the piecemeal rejection of the various components and ranges set forth in the claims appears to be based mainly, if not solely, on hindsight (using the present application as a guide) rather than any identifiable teaching or suggestion contained in the cited art. It is the inventors, not the cited art, that understand and teach the relationship between pH and its affect on sodium hypochlorite stability, and gel stability, and how to strike the delicate balance. That is the very essence of invention.

In view of the foregoing, Applicants submit that the claims as amended are in allowable condition. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or that may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 13th day of June 2005.

Respectfully submitted,



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